OCT 2 4 2002

K023194

510(k) Summary

Submitter

LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, CA 95035
Contact: John E. Hughes
Date Prepared: October 23, 2002

Device Name

SURESTEP®PRO Professional Blood Glucose Management System
SURESTEP®FLEXX Professional Blood Glucose Management System
Common name: Glucose test system

Predicate Device

SURESTEP®PRO Blood Glucose Monitoring System

Device Description

The SURESTEPPRO and SURESTEPFLEXX Systems consist of a test strip (SURESTEPPRO Test Strips), a reflectance photometer, quality control solutions, and linearity solutions. Ancillary devices to aid in obtaining blood samples (e.g. lancing devices) and external data management computer software designed to facilitate storage and retrieval of results are also provided.

A sample is placed on a test strip and inserted into the reflectance photometer. Glucose in the sample reacts with oxygen in a glucose oxidase–catalyzed reaction yielding gluconic acid and hydrogen peroxide. A second enzyme, peroxidase, mediates transformation of indicator dyes into products with a blue color. The intensity of the resulting blue color is proportional to the concentration of glucose in the sample. The meter measures the amount of light reflected by this blue colored product and converts the reflectance data into a glucose concentration that is displayed on a liquid crystal display. The user adjusts the meter response for each lot of test strips by entering a calibration code specific to that lot of test strips.

Intended Use

The SURESTEP®PRO and the SURESTEPFLEXX Professional Blood Glucose Management Systems are for *in vitro* diagnostic use for the quantitative measurement of glucose in venous, capillary, arterial, and neonatal whole blood samples. These systems can also be used by lay users at home.

Comparison to Predicate Device

The existing labeling for the SURESTEPPRO Professional Blood Glucose Management System and the SURESTEPFLEXX Professional Blood Glucose Management System has

been simplified to increase understanding and provide clear explanations of the performance capabilities and the performance limitations of the system.

Conclusion

The modified SURESTEPPRO Professional Blood Glucose Management System and the SURESTEPFLEXX Professional Blood Glucose Management System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 2 4 2002

Mr. John E. Hughes
Manager, Regulatory Submissions
LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, CA 95035-6312

Re: k023194
Trade/Device Name: SureStep®Pro Professional Blood Glucose Management System
SureStep®Flexx Professional Blood Glucose Management System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW; CGA
Dated: September 24, 2002
Received: September 25, 2002

Dear Mr. Hughes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: _____

Device Name: SURESTEP®PRO Professional Blood Glucose Management System
SURESTEP®FLEXX Professional Blood Glucose Management System

Indications for Use:

The SURESTEP®PRO and the SURESTEPFLEXX Professional Blood Glucose Management Systems are for *in vitro* diagnostic use for the quantitative measurement of glucose in venous, capillary, arterial, and neonatal whole blood samples. These systems can also be used by lay users at home.

Dean Cooper

(Division Sign-Off)
Division of Clinical Laborator
510(k) Number K023194

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____ OR Over-the-Counter Use ✓
(Per 21 CFR 801.109)